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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,435	08/29/2001	John Richard Schwier	342312003401	8122

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,435

Applicant(s)

SCHWIER ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/29/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Requirement for Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-21, drawn to a first process of making a composition containing a cyclopeptide, carbohydrate, and a granular diluent or carrier, classified in class 530, subclass 9.
- II. Claims 22-24, drawn to a first composition containing a cyclopeptide and other molecules, classified in class 530, subclass 333.
- III. Claim 25, drawn to a first process of use of a composition, classified in class 514, subclass 2.
- IV. Claims 26-47, drawn to a second process of making a composition containing a cyclopeptide, carbohydrate, and a non-granular diluent or carrier, classified in class 530, subclass 9.
- V. Claims 48-50, drawn to a second composition containing a cyclopeptide and other molecules, classified in class 530, subclass 333.
- VI. Claim 51, drawn to a second process of use of a composition, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product (granules) can be made by other materially different processes, as is evidenced by the claims themselves, namely the process of Invention IV, or a process that makes a composition containing an echinocandin containing antifungal product in a white to off-white powder/cake (See Merck & Co., Inc., Cancidas® (caspofungin acetate) <http://virtualtrials.com/news3.cfm?item=613>). Therefore, these Inventions are patentably distinct.

The process of making Invention I and process of using Invention III, are related as either making or using the composition containing granules. However, the processes of using and making Inventions differ in the product used and/or the steps and results of the respective processes. They have different modes of operation, they have different functions, and/or they have different effect. One would not have to practice the various processes at the same time to practice just one process alone. Therefore, these Inventions are patentably distinct.

Inventions I and IV are related as processes of making a composition (granules). However, the inventions use different products and steps to attain their respective results, i.e. Invention IV's use of a granulating agent in step 1. Therefore, these Inventions are patentably distinct.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product (granules) can be made by other materially different processes, as is evidenced by the

claims themselves, namely the process of Invention IV, or a process that makes a composition containing an echinocandin containing antifungal product in a white to off-white powder/cake (See Merck & Co., Inc., Cancidas® (caspofungin acetate) <http://virtualtrials.com/news3.cfm?item=613>). Therefore, these Inventions are patentably distinct.

The process of making Invention I and process of using Invention VI, are related as either making or using a composition containing granules. However, the processes of using and making Inventions differ in the product used and/or the steps and results of the respective processes. They have different modes of operation, they have different functions, and/or they have different effect. One would not have to practice the various processes at the same time to practice just one process alone. Therefore, these Inventions are patentably distinct.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case, the product could be used in alternative fields, which would not involve oral administration to a host, such as treating botanical diseases (Dutch elm disease) or treating water-damaged materials such as art work (see <http://www.mold-survivor.com/suggestedtreatments.htm>, ¶ 4, regarding use of antifungal Nystatin in alternative fields). Therefore, these Inventions are patentably distinct.

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

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made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product (granules) can be made by other materially different processes, as is evidenced by the claims themselves, namely the process of Invention I, or a process that makes a composition containing an echinocandin containing antifungal product in a white to off-white powder/cake (See Merck & Co., Inc., Cancidas® (caspofungin acetate) <http://virtualtrials.com/news3.cfm?item=613>). Therefore, these Inventions are patentably distinct.

Inventions II and V are related as compositions containing granules. However, each Invention was created using different products and steps, and thus different compositions, i.e. Invention V contains a granulating agent as part of its composition (more specifically as in claim 46, 'polyvinylpyrrolidone'). Therefore, these Inventions are patentably distinct.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case, the product could be used in alternative fields, which would not involve oral administration to a host, such as treating botanical diseases (Dutch elm disease) or treating water-damaged materials such as art work (see <http://www.mold-survivor.com/suggestedtreatments.htm>, ¶ 4, regarding use of antifungal Nystatin in alternative fields). Therefore, these Inventions are patentably distinct.

The process of using Invention III and process of making Invention IV, are related as either making or using the composition containing granules. However, the processes of using and making Inventions differ in the product used and/or the steps and results of the respective

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processes. They have different modes of operation, they have different functions, and/or they have different effect. One would not have to practice the various processes at the same time to practice just one process alone. Therefore, these Inventions are patentably distinct.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case, the product could be used in alternative fields, which would not involve oral administration to a host, such as treating botanical diseases (Dutch elm disease) or treating water-damaged materials such as art work (see <http://www.mold-survivor.com/suggestedtreatments.htm>, ¶ 4, regarding use of antifungal Nystatin in alternative fields). Therefore, these Inventions are patentably distinct.

Inventions III and VI are related as process of use for a composition. However, both processes use different compositions, namely Invention VI uses a composition that contains a granulating agent as part of its composition (more specifically as in claim 46, 'polyvinylpyrrolidone'). Therefore, these Inventions are patentably distinct.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product (granules) can be made by other and materially different processes, as is evidenced by the claims themselves, namely the process of Invention I, or a process that makes a composition

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containing an echinocandin containing antifungal product in a white to off-white powder/cake

(See Merck & Co., Inc., Cancidas® (caspofungin acetate)

<http://virtualtrials.com/news3.cfm?item=613>). Therefore, these Inventions are patentably distinct.

The process of making Invention IV and process of using Invention VI, are related as either making or using the composition of Invention V. However, the processes of using and making Inventions differ in the product used and/or the steps and results of the respective processes. They have different modes of operation, they have different functions, and/or they have different effect. One would not have to practice the various processes at the same time to practice just one process alone. Therefore, these Inventions are patentably distinct.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case, the product could be used in alternative fields, which would not involve oral administration to a host, such as treating botanical diseases (Dutch elm disease) or treating water-damaged materials such as art work (see <http://www.mold-survivor.com/suggestedtreatments.htm>, ¶ 4, regarding use of antifungal Nystatin in alternative fields). Therefore, these Inventions are patentably distinct.

Requirement for Species Restriction

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) The many different echinocandin compounds, encompassed by claims 1-4, 26-29;
- b) The many different carbohydrate molecules, encompassed by claims 5-6, and 30-31;
- c) The many different granular diluents/carriers, encompassed in claims 9-11;
- d) The many different non-granular diluents/carriers, encompassed by claims 34-36; and
- e) The many different excipients, encompassed by claims 21 and 47.

Applicant is required under 35 U.S.C. 121 to enumerate all of the specific components of the composition (that clearly delineates a searchable, chemical structure representing the elected invention/composition) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable; i.e. a specific echinocandin, a specific carbohydrate, etc. Currently, claims 1 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Request for Preliminary Set of Amended Claims

3. As part of the election, Applicant is requested to submit a preliminary set of amended claims, directed to the elected invention, which do not contain any dependencies to any other non-elected inventions (claims) or improper multiple dependent claims, and which are fully descriptive of and include all limitations to that set of claims representing the elected invention.

Conclusion

4. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
March 5, 2002

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal line extending to the right.

MICHAEL V. MELLER
PATENT EXAMINER